



## Support SB428 - Sponsored by Senator Kaufmann Controlling Cancer Depends on Increased Access to Clinical Trials

In the 1940s, fewer than one out of every four women survived localized breast cancer for five years or more. Through the development and use of improved early detection and treatment methods, the five-year survival rate for localized breast cancer has increased to 96% today. **Without clinical trials, these new screening and treatment methods would have languished in the laboratory – never reaching the patient.** Participation in clinical trials offers patients the opportunity to access cutting-edge treatments – for many patients these trials offer the best chance for survival.

Currently, only 3% of cancer patients enroll in clinical trials. Part of the problem is that many health insurers refuse coverage for a patient's **routine care costs** if the patient enrolls in a clinical trial – effectively denying access to life saving treatment. **The American Cancer Society and the Montana Cancer Control Coalition asks the Montana legislature to enact legislative measures *this year* that will assure coverage for routine patient care costs when a patient enrolls in a clinical trial. Support SB428.**

### Clinical Trials are the Key to Further Advances in Cancer Care

We have made many advances in the last 30 years in cancer treatment; however, there are still many cancers for which no effective treatment exists. For example, pancreatic cancer is the fourth leading cause of cancer-related death in men and women. While treatment options exist that can extend survival and relieve symptoms in many patients, there is currently no cure for this disease. For all stages of pancreatic cancer combined, the overall one-year survival rate is a mere 21%, while the five-year rate is only about 5%. **For most pancreatic cancer patients, and many others with rare cancers, new and innovative treatments are the only hope for a cure.**

Clinical trials involve the systematic testing of new strategies for prevention, early detection, and treatment of diseases. They are a critical step in the treatment development process and are literally the bridge between research discovery of a new drug and widespread use of the drug by the patients who need it. During the trial, the new treatment goes through several different phases of testing including comparison with the best standard therapy available.

Access to clinical trials is important for patients with all types of cancer – even for those that already have an effective curative treatment. For many cancers, there are standard treatments that are very effective at killing cancer, but may cause highly undesirable side effects such as heart or kidney failure, hair loss, severe nausea, etc. More effective treatments aimed at reducing side effects and improving quality of life for people living with cancer are desperately needed. Development of these new treatments is dependent on clinical trials. In addition, increased research to improve access of medically underserved and minority patients to clinical trials is needed to ensure that clinical trials are available to all patients.

### The “Routine” in “Routine Patient Care Costs”

Routine patient care costs are costs for the care patients would receive regardless of whether or not they are receiving standard treatment or participating in a trial. These include cost from such things as blood work or physician visits – services a patient needs because they have cancer, not because they are participating in a trial. While these items are covered by the monthly premium a patient pays to their health plan – and are not questioned when a patient receives standard therapy – a health plan can currently deny coverage *for these same services* simply because the patient enrolls in a clinical trial.

- Routine patient care costs *do not* include the cost of the actual drug or research-related costs.
- **Currently, Medicare beneficiaries have coverage for routine patient care costs when they enroll in a clinical trial. It is critical to the continued advancement of cancer treatment options that coverage is extended to those in the under-65 privately insured population.**

## **Assuring Access to Clinical Trials is Not Costly**

Evidence from numerous studies has shown that patient care in clinical trials costs approximately the same as care delivered in standard therapy. In some cases, because the third-party payer is not billed for the drug or treatment under investigation, the costs associated with care in a clinical trial can actually be less than the care delivered in standard therapy.

- A study at Memorial Sloan-Kettering Cancer Center in New York City showed that the overall average cost of treating clinical trial patients was 17% *less* than treating patients receiving standard care.<sup>1</sup>
- Authors of a study conducted at Kaiser Permanente found that the cost of medical care for enrollees in clinical trials without bone marrow transplant were no higher than for patients who were not enrolled in a trial. Kaiser further states, "Kaiser has been participating in cancer clinical trials without substantial increases in the direct costs of medical care."<sup>2</sup>

## **Cancer Patients are Depending on Legislative Action**

Each year, our nation invests billions of dollars in research; however, if patients do not have access to clinical trials, the general patient population will never benefit from these research investments. To ensure that more cancer patients have access to potentially life-saving clinical trials, the American Cancer Society and MTCCC urge the Montana Legislature to consider legislation – such as SB428 – that would eliminate the coverage barrier for routine care costs for all privately insured patients. We are confident that clinical trials legislation, which includes the basic principles outlined below, will reduce the death toll of this disease:

- **Ensure Access to High Quality, Independently-Reviewed Clinical Trials**

Patients must have access to all phases of clinical trials approved or funded by the National Institutes of Health (NIH), a cooperative group or center of the NIH, the Department of Veterans Affairs, the Department of Defense, the Food and Drug Administration, and qualified non-governmental research entities, such as the American Cancer Society, that adhere to rigorous standards for human participant protections. **It is critical that cancer patients have full access to these potentially life-saving treatments.**

- **Ensure Coverage of Routine Patient Care Costs**

The American Cancer Society advocates that health plans provide coverage for routine care costs regardless of whether or not a patient is in a clinical trial or receiving standard therapy. We are not asking the health plan to cover research-related costs or even the cost of the actual drug or device under investigation. **We are asking only that the care covered by patients' premiums when they receive standard therapy also be covered when a patient enrolls in a clinical trial.** The American Cancer Society asks Congress to provide patients with the assurance that coverage for benefits and services will not be taken away simply because they have enrolled in a clinical trial.

**It is important to remember that the standard treatment of today was investigational only yesterday.**

Providing cancer patients with access to the full range of high quality potentially life-saving treatments available in clinical trials will help reduce suffering, prevent early deaths, and enhance scientific advancements – providing hope to the millions of cancer patients in the United States.

**The American Cancer Society and Montana Cancer Control Coalition strongly urge the Montana Legislature to enact legislative measures *this year* that will assure coverage for routine patient care costs when a patient enrolls in a clinical trial. Support SB 428.**

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<sup>1</sup> Quirk J, Schrag D, Radzyner M, *et al.* Clinical trial costs are similar to and may be less than standard care and inpatient (InPT) charges at an academic medical center (AMC) are similar to major, minor, and non-teaching hospitals. *Proc Am Soc Clin Oncol* 2000;19:433a. (abstr 1696).

<sup>2</sup> Fireman BH, Fehrenbacher L, Gruskin EP, Ray GT. Cost of care for patients in cancer clinical trials. *J Natl Cancer Inst* 2000;92:136-42.